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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/565,301

04/19/2006

Toshikazu Nakamura

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SUITE 800

WASHINGTON, DC 20006-1021

EXAMINER

LAU, JONATHAN S

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

03/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,301	NAKAMURA ET AL.	
	Examiner	Art Unit	
	Jonathan S. Lau	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 1-11, 19 and 23-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-18 and 20-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4 pgs / 20Jan2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is the national stage entry of PCT/JP05/05741, filed 28 Mar 2005; and claims benefit of foreign priority document JAPAN 2004-097047, filed 29 Mar 2004; currently an English language translation of this foreign priority document has not been filed.

Claims 1-34 are pending in the current application. Claims 1-11 and 23-33, drawn to non-elected inventions, are withdrawn. Claim 19, drawn to non-elected species, is withdrawn. Claims 12-18 and 20-22 are examined on the merits herein.

Election/Restrictions

Applicant's election without traverse of the invention of Group II, claims 12-22, in the reply filed on 01 Feb 2008 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-11 and 23-33 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 01 Feb 2008.

Applicant's election of species of formula (II) in element (b) from I the list of compounds in claims 7, 18 or 34. Applicants further elect hydrogen from species R¹, sulfate group from species R², optionally substituted carboxyl group from species R³,

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hydrogen from species R⁴, 0 from species group n or m in the reply filed on 01 Feb 2008 is acknowledged.

Claim 19, drawn the species wherein the hydroxy group at position 6 of at least one of the glucosamine residue(s) is sulfated, does not read upon the species wherein R¹ is hydrogen. Therefore claim 19 is withdrawn.

Claim Objections

Claim 13 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 13 recites a "method of promoting HGF production according to claim 12, wherein the hydroxy group at position 2 of at least one of the uronic acid residue(s) and/or the hydroxy group at positions 3 and/or 6 of at least one of the glucosamine residue(s) **may** be sulfated," emphasis added. Claim 13 does not require at least one of the groups to be sulfated. Therefore claim 13 does not further limit the subject matter of claim 12.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 34 includes the limitation "... wherein R¹, R³ and R⁴ represent hydrogen, R² represents sulfate group..." Claims 7 and 18 recite the limitation, "... R³ and R⁴ are different from each other and represent hydrogen or optionally substituted carboxyl group..." There is insufficient written description in the application as filed to support the limitation wherein R³ and R⁴ are the same, both hydrogen.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

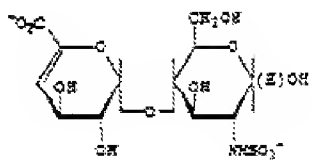
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12-18 and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Cahalon et al. (US Patent Application Publication 2003/0130230, published 10 Jul 2003, cited in PTO-892) as evidenced by Seidel et al. (British Journal of Haematology, 1999, 105, p641-647, cited in PTO-892).

Cahalon et al. discloses a method for treating symptoms associated with the development and metastasis of malignancies comprising administering a heparin-

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derived saccharide compound (page 7, paragraphs 58, 59 and 52). Cahalon et al. discloses the administration of the compound to a mammal, a mouse (page 11, paragraph 77). Cahalon et al. discloses the use of compound DS 1145



(page 16, table entry DS 1145), the elected specie of

compound, meeting the limitations of instant claims 12-15, 18, 20, 21 and 34. Cahalon et al. discloses the compound isolated from low molecular weight heparin or produced by the action of heparinase on natural sources of heparin, or high molecular weight heparin (page 3, paragraph 24), meeting the limitation of instant claim 16. Cahalon et al. envisions compounds having antimetastatic and anti-inflammatory activity having negligible anticoagulant activity (page 2, paragraph 16), meeting the limitation of instant claim 22. Cahalon et al. discloses the heparin-derived saccharide compound exhibits a regulator effect that includes both up regulation and down regulation of cytokine activity and may elicit the secretion of active cytokine (page 6, paragraphs 31 and 32). As evidenced by Seidel et al., it is known that soluble heparin molecules induce an increase in the cytokine hepatocyte growth factor (HGF) (page 641, left column, line 1 and right column, lines 4-8). Therefore, it is apparent from what is disclosed that one practicing the method disclosed by Cahalon et al. would inherently be practicing the instantly claimed method of promoting HGF production.

Claim 17 recites a method of using a product drawn to a product-by-process. “[E]ven though product-by-process claims are limited by and defined by the process,

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determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.). See MPEP 2113.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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